MAIL STOP APPEAL BRIEF-PATENTS
Attorney Docket No. 27072U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DIETZEL et al.		Examiner:	ACEVEDO, J. H. A.
Serial No.:	10/559,383	Art Unit:	1616
Filed:	December 6, 2005	Conf. No.:	3631

For: **FORMOTEROL AND CICLESONIDE COMBINATION**

APPEAL BRIEF

This is an appeal to the Board of Patent Appeals and Interferences from the decision of Examiner J.H.A. Acevedo, mailed October 13, 2010, rejecting claims 1-4 and 6-11. Appellants timely filed a Notice of Appeal on March 14, 2011, making this Appeal Brief due by May 14, 2011. Accordingly, this paper is timely filed.

1. Table of Contents

2. The Real Party in Interest

The real party in interest in this appeal is NYCOMED GmbH.

3. Related Appeals and Interferences

Appellants are not aware of any other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

4. Status of Claims

The status of the claims is as follows upon filing of this Appeal Brief:

Claims cancelled: 5

Claims withdrawn from consideration but not cancelled: NONE

Claims pending: 1-4 and 6-11

Claims objected to: None

Claims allowed: None

Claims rejected: 1-4 and 6-11

The claims on appeal are 1-4 and 6-11.

5. Status of Amendments

Appellants filed a Preliminary Amendment on December 6, 2005, in which claims 1-11 were amended.

The Examiner issued an Official Action on July 23, 2009 rejecting claims 1-11 and objecting to claims 2, 4, 8 and 10. Appellants filed a Response and Amendment January 22, 2010 wherein claims 1-2, 4, 8 and 10 were amended.

The Examiner issued a final Official Action dated April 7, 2010 wherein claims 1-11 were rejected and claim 4 was objected to. Appellants filed a Request for Continued Examination (RCE), along with an Amendment and Response on October 5, 2010, in which claims 1-2, 4 and 6 were amended and claim 5 was canceled.

No further amendments have been made to the claims.

As such, Appellants submit that claims 1-4 and 6-11 are the currently pending claims on appeal. The claims listed in the Claims Appendix herein incorporate the claim amendments of the aforementioned Amendment and Response.

6. Summary of Claimed Subject Matter

Pending independent claim 1 claims a pharmaceutical suspension formulation comprising

a. as a first active ingredient, particles of R,R-formoterol or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

b. as a second active ingredient, particles of ciclesonide or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation, and

c. a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof,

wherein said first active ingredient and said second active ingredient are the sole active ingredients in said pharmaceutical suspension formulation, and are readily dispersible, and upon redispersion do not flocculate as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient.

Basis for this claim is found in the specification on page 4, paragraphs 1-2 and 4-5, page 5, paragraph 1, page 10 in the Examples, and originally filed claim 5.

7. Grounds of Rejection to be Reviewed on Appeal

A. Rejection of claims 1, 3-4, 6, 9 and 11 under 35 USC § 103(a)

Whether the identified claims are unpatentable under 35 USC § 103(a) as being unpatentable over Aberg et al. (US Patent No. 5,795,564) in view of Burt (US Publication No. 2002/0030068), Garcia-Marcos et al. and Calatayud et al. (US Patent No. 5,482,934).

B. Rejection of claims 2 and 7-8 under 35 USC § 103(a)

Whether the identified claims are unpatentable under 35 USC § 103(a) as being unpatentable over Aberg et al. (US Patent No. 5,795,564) in view of Burt (US Publication No. 2002/0030068), Garcia-Marcos et al. and Calatayud et al. (US Patent No. 5,482,934) and further in view of Fassberg et al. (US Patent No. 5,474,759).

C. Rejection of claims 1, 3, 9 and 11 under 35 USC § 103(a)

Whether the identified claims are unpatentable under 35 USC § 103(a) as being unpatentable over Gavin (WO 01/78738) in view of Calatayud et al. (US Patent No. 5,482,934).

D. Rejection of claims 2, 4, 7 and 8 under 35 USC § 103(a)

Whether the identified claims are unpatentable under 35 USC § 103(a) as unpatentable over Gavin (WO 01/78738) in view of Calatayud et al. (US Patent No. 5,482,934) and further in view of Fassberg et al. (US Patent No. 5,474,759).

E. Rejection of claims 2, 4, 7-8 and 10 under 35 USC § 103(a)

Whether the identified claims are unpatentable under 35 USC § 103(a) as unpatentable over Gavin (WO 01/78738) in view of Calatayud et al. (US Patent No. 5,482,934) and further in view of Keller et al. (WO 00/07567).

F. Provisional rejection of claim 1 on the ground of obviousness-type double patenting

Whether the identified claim is unpatentable on the ground of obviousness-type double patenting over claim 6 of USSN 10/537,356 in view of Burt (US Publication No. 2002/0030068) and Aberg et al. (US Patent No. 5,795,564).

8. Arguments

A. Rejection of claims 1, 3-4, 6, 9 and 11 under 35 USC § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 USC § 103(a) as being unpatentable over Aberg et al. (US Patent No. 5,795,564) in view of Burt (US Publication No. 2002/0030068), Garcia-Marcos et al. and Calatayud et al. (US Patent No. 5,482,934) is improper and should be reversed.

The state of the law

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under 35 USC § 103 by: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of non-obviousness.

Furthermore, to establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention

does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Also, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would have been obvious to modify the references to produce the present invention. See *Ex parte Clapp*, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the ordinary skilled artisan would have found the claimed invention to have been obvious in light of the reference teachings. *Id*. at 974.

The presently claimed subject matter

Independent claim 1 is directed to "[a] pharmaceutical suspension formulation comprising

a. as a first active ingredient, particles of R,R-formoterol or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

b. as a second active ingredient, particles of ciclesonide or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation, and

c. a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof,

wherein said first active ingredient and said second active ingredient are the sole active ingredients in said pharmaceutical suspension formulation, and are readily dispersible, and upon redispersion do not flocculate as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient.

No *prima facie* case of obviousness has been properly established

It is submitted that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, none of Aberg et al., Burt, Garcia and/or Calatayud et al. teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In contrast to the presently claimed subject matter, Aberg et al. discloses a metered dose inhaler containing a suspension formulation comprising only R,R-formoterol fumarate dihydrate as the active ingredient. As such, Aberg et al. is absolutely silent regarding the presently claimed formulation comprising particles of R,R-formoterol *and ciclesonide* as the *sole active ingredients* being readily dispersible, and upon redispersion, not flocculating as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient as presently claimed.

There is absolutely no teaching in Aberg et al. regarding the presently claimed combination. Therefore, Aberg et al. do not "teach or suggest all the limitations of the claims" as required by *In re Wilson*. The Burt et al. reference does not remedy the deficiencies of Aberg et al. Burt et al. merely describes suitable alternative propellants include HFA-134a (1,1,1,2-tetrafluoroethane) and HFA-227 (1,1,1,2,3,3,3-heptafluoropropane) which may be combined with a combination of formoterol and an inhaled corticosteroid. As such, Burt et al. does not discuss or contemplate a pharmaceutical suspension formulation comprising particles of R,R-formoterol and ciclesonide as the sole active ingredients being readily dispersible, and upon redispersion, not flocculating as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient as presently claimed.

The Garcia reference does not remedy the deficiencies of the Aberg et al. and Burt et al. references. Garcia discusses the combination of formoterol and budesonide. More specifically, Garcia discusses improved lung function when combined with both low and high doses of budesonide in comparison to administering budesonide alone. Thus, Garcia does not teach a pharmaceutical suspension formulation comprising particles of R,R-formoterol and ciclesonide as the sole active ingredients being readily dispersible, and upon redispersion, not flocculating as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient as presently claimed.

The Calatayud et al. reference does not remedy the deficiencies of the aforementioned references since it does not discuss anywhere the use of R,R-formoterol in conjunction with ciclesonide as presently claimed.

Therefore, the cited references do not establish a *prima facie* case of obviousness against the presently claimed subject matter for at least the reason that the cited references do not teach each and every element of the presently pending claims as required by *In re Wilson*.

Without a sufficient teaching, the Examiner cannot "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements" in such a way as to arrive at the presently claimed subject matter with a reasonable expectation of success as required by *KSR* and *Amgen*, supra.

Furthermore, appellants take issue with the Examiner's statements that appellants have only argued against the cited references individually and not as a combination. While appellants have discussed the references separately, appellants have not provided a piecemeal presentation in their response to the Examiner's improper rejection of the claims.

Appellants have simply stated what the law requires the Examiner to demonstrate to establish a *prima facie* case of obviousness. Further, appellants have discussed what the cited references teach - as well as what they do not teach – vis-à-vis those requirements. Even further, in contrast to the Examiner's allegation, appellants have discussed the references as a combination. In particular, appellants have pointed out that, upon reading the combined teachings of the cited references, a person of ordinary skill in the art would not be motivated to prepare the presently claimed subject matter.

As such, the rejected claims are not obvious under 35 U.S.C. §103(a) and appellants respectfully request that the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 1, 3-4, 6, 9 and 11.

B. Rejection of claims 21-24 and 26-29 under 35 USC § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 USC § 103(a) as being unpatentable over Aberg et al. (US Patent No. 5,795,564) in view of Burt (US Publication No. 2002/0030068), Garcia-Marcos et al. and Calatayud et al. (US Patent No. 5,482,934) and further in view of Fassberg et al. (US Patent No. 5,474,759) is improper and should be reversed.

Appellants respectfully submit that none of the cited references, alone or in combination, render Appellants' pending claims obvious for at least the following reasons.

The requirements for establishing a *prima facie* case of obviousness are outlined above in section 8A and are incorporated herein by reference. Further, all of the cited references other than Fassberg et al. (US Patent No. 5,474,759) are discussed in detail in section 8A and for the sake of brevity, appellants incorporate the discussion of all references contained in section 8A herewith.

The Examiner asserts that Fassberg et al. teaches pharmaceutical aerosol formulations comprising a medicament, a surfactant, an excipient and a propellant and thus, renders obvious claims 2 and 7-8 which specifically recite a surfactant. Thus, the Examiner relies on Fassberg et al. for its alleged disclosure of surfactants and excipients.

Appellants respectfully note, however, that there is nothing contained in the Fassberg et al. reference that remedies the deficient teachings of the Aberg et al., Burt, Garcia-Marcos et al. and Calatayud et al. references. Therefore, the rejected claims are free of the prior art for at least the reasons discussed above in Section 8A.

As such, claims 2 and 7-8 are not obvious under 35 U.S.C. §103(a) and appellants respectfully request that the Board of Patent Appeals and Interferences to reverse the present rejection of these claims.

C. Rejection of claims 1, 3, 9 and 11 under 35 USC § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 USC § 103(a) as being unpatentable over Gavin (WO 01/78738) in view of Calatayud et al. (US Patent No. 5,482,934) is improper and should be reversed.

Appellants respectfully submit that none of the cited references, alone or in combination, render Appellants' claims 1, 3, 9 and 11 obvious for at least the following reasons.

The requirements for establishing a *prima facie* case of obviousness are outlined above in section 8A. Further, the Calatayud et al. reference is discussed in detail in section 8A. For the sake of brevity, appellants incorporate the discussion of the Calatayud et al. reference contained in section 8A herewith.

The Examiner asserts that Gavin et al. teaches medicinal compositions comprising (R,R)-formoterol and rofleponide as well as a propellant such as 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane or mixtures thereof. Thus, the Examiner relies on Gavin et al. for its alleged disclosure of formoterol with rofleponide, a corticosteroid.

Appellants respectfully note, however, that the Gavin reference requires an active ingredient other than those presently claimed. In particular, the presently

pending claims recite that "the sole active ingredients" are "particles of R,R-formoterol or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation," and "particles of ciclesonide or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation".

As such, Gavin's disclosure cannot render the presently claimed subject matter obvious because it does not teach "[a] pharmaceutical suspension formulation comprising" only the specific active ingredients of the presently claimed subject matter. Instead, Gavin requires the presence of the active ingredient rofleponide.

Accordingly, Gavin does not teach each and every element of the presently pending claims as required by *In re Wilson*.

As such, the presently rejected claims are not obvious under 35 U.S.C. §103(a) and appellants respectfully request that the Board of Patent Appeals and Interferences to reverse the present rejection of claims 1, 3, 9 and 11.

D. Rejection of claims 2, 4, 7 and 8 under 35 USC § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 USC § 103(a) as unpatentable over Gavin (WO 01/78738) in view of Calatayud et al. (US Patent No. 5,482,934) and further in view of Fassberg et al. (US Patent No. 5,474,759) is improper and should be reversed.

The requirements for establishing a *prima facie* case of obviousness are outlined above in section 8A. Also, all cited references have been discussed in detail in previous

sections. For the sake of brevity, the discussion of the relevant authority and all references are incorporated herein in their entirety.

The rejected claims are free of the prior art for the reasons discussed in the above sections and Appellants' arguments stated above are incorporated herein by reference in their entirety. Namely, the primary Gavin reference requires the presence of an active ingredient other than those specifically recited in the presently pending claims. In particular, Gavin requires the presence of the active ingredient "rofleponide" in his pharmaceutical formulation. As such, Gavin's disclosure cannot render the presently claimed subject matter obvious because it does not teach "[a] pharmaceutical suspension formulation comprising" only the specific active ingredients of the presently claimed subject matter.

Accordingly, Gavin does not teach each and every element of the presently pending claims as required by *In re Wilson*.

Accordingly, for each of the reasons outlined above, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 2, 4, 7 and 8.

E. Rejection of claims 2, 4, 7-8 and 10 under 35 USC § 103(a)

Appellants respectfully submit that the rejection of the identified claims under 35 USC § 103(a) as being unpatentable over Gavin (WO 01/78738) in view of Calatayud et al. (US Patent No. 5,482,934) and further in view of Keller et al. (WO 00/07567) is improper and should be reversed.

The requirements for establishing a *prima facie* case of obviousness are outlined

above in section 8A. Also, all references other than the Keller et al. reference are discussed in detail in previous sections. For the sake of brevity, the discussion of the relevant authority and all references other than the Keller et al. reference is incorporated herein in its entirety.

The Examiner asserts that Keller et al. teaches that the inclusion of solid salts of cromoglycic acid and/or nedocromil as a vehicle at non-therapeutically or non-prophylactically effective concentrations improves the dispersion characteristics and the chemical and physical stability or active ingredients which are sensitive to moisture and are present in pharmaceutical aerosol suspension formulations.

Thus, the Examiner relies on Keller et al. for its alleged disclosure that the inclusion of disodium cromoglycate or nedocromil sodium to formulations can be used to stabilize moisture-sensitive compounds, such as formoterol fumarate as well as to reduce the tendency to adhesion of electrostatically charged active compounds, such as micronized corticosteroids.

The rejected claims are free of the prior art for the reasons discussed above and Appellants' arguments stated above are incorporated herein by reference in their entirety. Namely, the primary Gavin reference requires the presence of an active ingredient other than those specifically recited in the presently pending claims. In particular, Gavin requires the presence of the active ingredient "rofleponide" in his pharmaceutical formulation. As such, Gavin's disclosure cannot render the presently claimed subject matter obvious because it does not teach "[a] pharmaceutical suspension formulation comprising" only the specific active ingredients of the presently claimed subject matter. Accordingly, Gavin does not teach each and every element of

the presently pending claims as required by *In re Wilson.* None of the secondary references cited by the Examiner remedy the deficient teachings of Gavin.

Accordingly, for each of the reasons outlined above, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 2, 4, 7-8 and 10.

F. Provisional rejection of claim 1 on the ground of obviousness-type double patenting

Appellants respectfully submit that the provisional rejection of the identified claim on the ground of obviousness-type double patenting over claim 6 of USSN 10/537,356 in view of Burt and Aberg et al. is improper and should be reversed.

First, appellants note that the '356 application has now been issued as US Patent No. 7,879,833. Claim 6 of the '833 patent recites:

"A pharmaceutical composition comprising a fixed combination of active compounds consisting of the active compound ciclesonide or an epimer thereof and the active compound R,R-formoterol or a salt, in an administration form suitable for inhalative administration by means of a powder inhaler, wherein the active compound ciclesonide or an epimer thereof and the active compound R,R-formoterol or a salt, are the sole active ingredients in the composition and are present ready mixed in a fixed combination."

In contrast, presently pending claim 1 recites:

"A pharmaceutical suspension formulation comprising

a. as a first active ingredient, particles of R,R-formoterol or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

b. as a second active ingredient, particles of ciclesonide or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation, and

c. a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof,

wherein said first active ingredient and said second active ingredient are the sole active ingredients in said pharmaceutical suspension formulation, and are readily dispersible, and upon redispersion do not flocculate as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient.

In view of the clearly divergent scopes of the claims at issue, Appellants respectfully submit that issuance of presently pending claim 1 would not be an unjustified or improper timewise extension of the right to exclude granted by claim 6 of the '833 patent.

Accordingly, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present provisional rejection of pending claim 1.

If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

Date: May 12, 2011

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9. Claims Appendix

1. (Previously presented) A pharmaceutical suspension formulation comprising

   a. as a first active ingredient, particles of R,R-formoterol or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

   b. as a second active ingredient, particles of ciclesonide or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation, and

   c. a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof,

wherein said first active ingredient and said second active ingredient are the sole active ingredients in said pharmaceutical suspension formulation, and are readily dispersible, and upon redispersion do not flocculate as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient.

2. (Previously presented) The pharmaceutical suspension formulation according to claim 1 comprising

   a. as a first active ingredient, particles of micronized R,R-formoterol, or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

b. as a second active ingredient, particles of micronized ciclesonide or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

c. ethanol,

d. a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and

e. optionally further comprising a surfactant,

wherein said first active ingredient and said second active ingredient are the sole active ingredients in said pharmaceutical suspension formulation, and are readily dispersible, and upon redispersion do not flocculate as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient.

3. (Previously presented) The pharmaceutical suspension formulation according to claim 1 containing less than 3% by weight of ethanol.

4. (Previously presented) The pharmaceutical suspension formulation according to claim 1 comprising

a. as a first active ingredient, particles of micronized R,R-formoterol, or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

b. as a second active ingredient, particles of micronized ciclesonide or a pharmaceutically acceptable salt thereof, said particles being suspended in the formulation,

c. a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof, and

d. further comprising a surfactant,

wherein said first active ingredient and said second active ingredient are the sole active ingredients in said pharmaceutical suspension formulation, and are readily dispersible, and upon redispersion do not flocculate as to prevent reproducing dosing of said first active ingredient and/or said second active ingredient.

5. (Cancelled)

6. (Previously presented) The pharmaceutical suspension formulation according to claim 1 which comprises R,R-formoterol fumarate dihydrate.

7. (Previously presented) The pharmaceutical suspension formulation according to claim 1 which comprises oleic acid as surfactant.

8. (Previously presented) The pharmaceutical suspension formulation according to claim 7 which comprises about 0.001 to 0.1 % (w/w) of oleic acid.

9. (Previously presented) The pharmaceutical suspension formulation according to claim 1 which comprises HFA 227 as propellant.

10. (Previously presented) The pharmaceutical suspension formulation according to claim 1 comprising disodium chromoglycate at a concentration which is not therapeutically and/or prophylactically active.

11. (Previously presented) The pharmaceutical suspension formulation according to claim 1, which is administered in a once daily dosing regimen.

10. Evidence Appendix

No information is appended under this section.

11. Related Proceedings Appendix

No information is appended under this section.